Weaponising medicine

Weaponising medicine: ''Tutti fratelli,'' no more

T Koch

The acceptance of military directives violating medical ethics and international covenants encouraged by the demonisation of the enemy by the US president in 2002 has effectively removed the right of medical personnel to refuse participation in internationally proscribed actions

Medicine and its traditional ethic of care is today a victim of the current conflict in Iraq and Afghanistan, its uniquely humanising mission rejected by US President George W Bush and his advisors. In denying the applicability of international agreements guaranteeing medicine's ecumenical role in this conflict they have transformed medicine into just another weapon of tactical significance. The result, predictable in retrospect, has been to make military physicians and nurses complicit—actively or passively—in what Litton calls an ''atrocity-producing situation'', resulting in detainee or prisoner abuse.[1]

From the first revelations of detainee torture in US detention camps (2004) to recent allegations of continued abuse (2006), the focus of international attention has shifted from the US prosecution of low ranking, non-commissioned military personnel to the context in which the atrocities they committed occurred. ''No one up the chain of command has ever been held accountable for what is in these horrifying images,'' Center for Constitutional Rights Director Bill Goodman said of recently published photographs of 2004 prisoner torture and abuse.[2] ''The situation in several areas violates international law and conventions on human rights and torture,'' said the UN Special Rapporteur on Torture following a 2006 investigation.[3]

The denial of international law and convention involved the overt disavowal of covenants and conventions that for almost 150 years required medical personnel in the US military to act within the guidelines of a Hippocratic vision of medicine. To understand how fundamental this change has been requires a brief review of the history of medicine's previously protected status and then a description of the method by which that history has been disavowed.

HISTORY

In June of 1859 a wealthy Genevan tourist, Jean-Henri Dunant, observed a furious battle between the armies of Emperor Napoleon III of France and Austria's Emperor Franz Joseph at Solferino near Castiglione, Italy.[4] When it was done Dunant saw in Castiglione that thousands of wounded soldiers of both armies were being cared for by Italian nurses and doctors.[5] ''*Tutti fratelli*,'' the nurses said when asked about their ecumenical treatment of the injured. ''They are all our brothers.''

Dunant's world changed forever in a way that changed ours. In 1862 Dunant wrote *Un Souvenire de Solferino*, a book about the brutality of the battle he had seen and the ecumenical nursing that followed it. His life's mission became not to tame war but to civilise it, arguing for international conventions and an organisation above war, one that would assure a measure of care and hope—the goals of medicine—amidst the carnage of the new, mechanised military.[5] In 1863 he founded the International Committee of the Red Cross and in 1864 organised the first Geneva Convention. Signed by 12 nations, including the United States, that convention and its successors made of the military medical professional a special case, a neutral resource and humanitarian asset, who served all combatants.

Those conventions were strengthened after the first world war, and again after the second world war. Germany's worst excesses occurred not on the battlefield but in the concentration camps, where prisoners not exterminated outright were put to hard labour or made the object of medical experimentation. Those atrocities began with official German rejection of international covenants of prisoner care and a subsequent willingness of civilian and military physicians to abandon traditional goals of ecumenical caring and healing.[6] As a result, medical personnel became military assets in violation of a series of international agreements, covenants, and protocols. Their failure to adhere to a more humanitarian medical ethic became the basis for charges at the Nuremberg Trials against German physicians of both crimes against humanity, where civilians were involved, and of war crimes when enemy soldiers were abused.[7]

THE CONTEXT

This time it is the US that has militarised medicine through the abrogation of international covenants. The result has been the denial of the role of humanitarian medicine, and a caring medical ethic, in US military detention camps. This was caused by US presidential decisions being translated into operational directives that concluded with a redefinition of the role of medical personnel active in military theatres. The theory has been that because the US is engaged in a struggle with terrorists who are not signatories to international agreements it is counterproductive at best and foolish at worst for the US to restrict its activities to those defined by international agreement, covenant, and treaty.[8] On 18 January 2002 President George W Bush decided that the Geneva Prisoner of War convention, and other international covenants, would not apply to suspect members of Al Quaeda and the Taliban captured in Afghanistan and Iraq by US troops.

Referenced in a supporting memo on 25 January by the then White House Council Robert Gonzalez,[9] the president's decision was preceded by a now famous, supporting memo written by Deputy Assistant Attorney General John Yoo and Special Counsel to the President Robert J Delahunty.[10] President Bush's decision was finalised in a February 2002 memorandum to the US vice-president and other staff, which is quoted by Jackson in a paper published in *The Army Lawyer*.[11]

War is a curious mixture of narcissism and rage, restrained only by a sense of reciprocity and a belief in common humanity. In his 2002 State of the Union address President Bush removed those restraints through his unilateral declaration of war against an ''axis of evil''[12] and the announcement of a bounty for opposition leaders, ''dead or alive'' (''I want justice'' Bush said. ''And there's on old poster out West…I recall, that said, 'Wanted, Dead or Alive'.'')[13] Opponents and their underlings were thus at once demonised, and dehumanised. The imposition of a bounty announced that traditional legal guidelines of fair treatment

and fair judgment would not be in play in this conflict.

In a 19 January 2002 memorandum US Secretary of Defense Donald Rumsfeld ordered the chairman of the joint chiefs of staff to inform combat commanders that: ''Al Quaeda and Taliban individuals...are not entitled to prisoner of war status for purposes of the Geneva Conventions of 1949''.[14] Prisoners, the memo continued, were to be treated ''humanely, and to the extent appropriate and consistent with military necessity, consistent with the Geneva Conventions of 1949''. What had been an absolute guide to military conduct thus became a thoroughly contingent guide secondary to the dictates of ''military necessity'' in the field. The ecumenical sense of Solferino—*Tutti fratelli*—to which the US had subscribed since 1864, was diminished as a result.

WEAPONISING MEDICINE

Dr David Tornberg, Deputy Assistant Secretary of Defense for Health Affairs, translated Secretary of Defense Rumsfeld's memorandum into an order that redefined the role of medical professionals in the US military. ''Physicians assigned to military intelligence…have no doctor patient relationship with detainees and, in the absence of life threatening emergency, have no obligation to offer medical aide''.[15] As professionals whose first concern is patient health and welfare irrespective of political or military allegiance…US military physicians were taken out of the game. ''A medical degree,'' Tornberg said, ''is not a 'sacramental vow'—it is a certification of skill.''[1] Under the Tornberg directive a medical degree becomes a practical diploma carrying no more ethical weight than a plumber's.

The logical conclusion of President George Bush's and Secretary of Defense Rumsfeld's memoranda, this was a dilution of the goals of medicine—healing and preventing harm—which ''has been a distinguishing mark of Hippocratic medicine since antiquity''.[16] If medicine has no special ethic then physicians are free to apply their skill to maximise the goals of military necessity irrespective of the effect on patients. Dr Tornberg's directive violated, however, a host of agreements to which the US is a signatory. In the Declaration of Havana in 1956—for example, the World Medical Association (WMA) stated in its *Regulations in Time of Armed Conflict*'' that ''medical ethics in time of armed conflict are identical to medical ethics in time of peace''.[17 18] This was the WMA's translation of postwar Geneva convention agreements following and in reaction to the Nuremberg trial experience.[19] The Tornberg rule rejected the very idea of a specific medical ethic whose guiding principle was that ''the primary obligation of a physician is his professional [medical] duty''.

The Tornberg rule also violated the first principle of the 1982 UN principles of medical ethics in the protection of prisoners and detainees: ''Health personnel, particularly physicians, charged with the medical care of prisoners and detainees have a duty to provide them with protection of their physical and mental health and treatment of disease of the same quality and standard as is afforded to those who are not imprisoned or detained''.[18]

PHYSICIAN COMBATANTS

The results were predictable. A host of activities proscribed by international convention and agreement appear to have become standard operating procedure for military personnel serving in US detention camps. Military physicians saw and treated detainees with wounds and injuries that could only have resulted from abuse by military personnel. Physicians caring for such patients—whose maltreatment has been the subject of widespread international discussion following publication of photographs of their distress[20]—who did not protest to superiors can be said to have been passively complicit in those abuses.

As active participants, some military physicians complied with orders to ''provide interrogators with [medical] information about prisoners' psychological vulnerabilities'', in violation of UN resolution 37/194 prohibiting physicians from ''any professional relationship with prisoners or detainees the purpose of which is not solely to evaluate, protect, or improve their physical and mental health''.[18]

Not only were military physicians ordered to volunteer any information that might be gained during treatment of a patient but some were also ordered to utilise patient medical records to uncover weaknesses that might be used by interrogators. This violated privacy protections enshrined in UN resolution 37/194 and in a World Medical Association agreement also adopted in the 1970s by the American Medical Association.[21] Some have argued that because military medical records are in the custody of military personnel their misuse was not the physician's responsibility.[22] None argue, however, that physicians used those records not for patient care alone but to maximise the potential of interrogations. The breach of medical ethics occurred not in their storage but their use by physicians for a purpose other than treatment.

Of course, the resulting ''harsh'' interrogations themselves were arguably in violation of the Third Geneva Convention's injunction that ''no physical or mental torture, nor any other form of coercion, may be inflicted on prisoners of war to secure from them information of any kind whatsoever''.[15] Failure of medical military personnel to protest those harsh interrogations[1 4 23] reflects a passive complicity, which violates the spirit of international conventions to which the US is a signatory, while active military participation in these activities represents an active violation of conventions and treaties.

In another arena of proscribed medical activity, in 2006 US military medical personnel force fed Guantanamo Bay detainees who were participating in a hunger strike to protest their detention and treatment. Despite a clear 1975 World Medical Association declaration that ''prisoners who refuse food and whom doctors consider capable of understanding the consequences should not be fed artificially''[24] participants were strapped into special chairs and force fed by medical personnel at Guantanamo Bay after being told: ''If they challenged the US, the US would challenge them back using these tactics''.[25]

Finally, former detainees have alleged that US medical personnel were involved in the long term use of drugs used in an attempt to extract information. British detainee Jamal Al-Harith—for example, recently described two years of injections of unknown drugs and continual physical abuse while in US detention and under US medical supervision.[26] Al-Harith said he was placed in shackles that prevented him from standing upright and that cut into his flesh, leaving scars on his wrists and ankles that required treatment.

PROTESTS: THE UNIFORM CODE OF MILITARY JUSTICE (UCMJ)

In theory, ''all doctors have obligations to report human rights abuses''.[19] In the US military they have had, at least since Nuremberg, the obligation to refuse orders that would require them to commit abuses. Why, then, were commissioned medical officers not the first to draw military and public attention to torturous acts? Why did they not refuse assignments that violated professional oaths and international covenants?

The so called Nuremberg defence against unlawful orders is codified in the US manual for Courts-Martial, established by executive order of the US president, to implement the provisions of the *Uniform Code of Military Justice*.[27] It states: ''It is a defense to any offense that the accused was acting pursuant to orders unless the accused

knew the orders to be unlawful or a person of ordinary sense and understanding would have known the orders to be unlawful''.[28]

It is unclear, however, whether a medical officer could argue successfully that medical activities in contravention of international agreements and treaties were unlawful. To protest as unlawful, orders to: assist in interrogations; force feed hunger strikers; plan and observe harsh interrogations, or provide information gained during medical treatment would have been to challenge the complete chain of US military command stretching from President George W Bush through his Secretary of Defense to the Deputy Assistant Chief of Defense for Medical Affairs, Dr Tornberg.

Under UCMJ articles the orders of a superior carry an a priori presumption of legality ''disobeyed at the peril of the subordinate'' who must prove an order was unlawful.[28] The penalties for refusing a lawful order are severe and may include ancillary charges of mutiny or sedition. Under the UCMJ, ''The dictates of a person's conscience, religion or personal philosophy'' are irrelevant in deciding whether or not an order is lawful''.[29] A defence on the basis of the Hippocratic oath as a professional standard would therefore almost certainly have been rejected by a military court judge. Indeed, Dr Tornberg forestalled this defence when he denied any special ethic to medical practitioners.

The only possible defence would have been to argue that ordering physicians to participate in Litton's ''atrocity-producing situations'' violated international covenants and treaties signed by the US that could not be abrogated by any individual, including the commander in chief. Article 6, paragraph 2 of the US constitution says that international treaties signed by the United States have the force of law in the US. However, this defence was forestalled by Yoo's 2002 memorandum which argued that: ''The constitutional text nowhere brackets president or federal power within the confines of international law.''[10]

CIVILIAN PREDISPOSITION

The Hippocratic vow to ''keep the ill from injustice'', and a historical definition of the physician as a moral agent responsible to and for the patient, have been diminished generally in recent years as medicine has become dependent on social institutions for its economic continuance.[30] As Jotterand put it in an article on civilian medical practice, gone are ''the simple certainties of an ethic based entirely on what the doctor thinks is good for the patient, and with it also any acquaintance with Hippocratic morality''.[31]

Younger physicians and nurses are increasingly trained in civilian life to see themselves not first and foremost as ethical advocates for the fragile patient with whom they are in relation but as agents of employers for whom the patient is not an ethical responsibility but a commercial client. The result has been ''the deprofessionalisation and the transformation of medicine into a vast industry, in which physicians lost their authority as professionals and became dependent on managed care organisations''.[29] In that industry injunctions to care and of personal responsibility in the physician/patient relation are increasingly replaced by corporate decisions, often made on the basis of cost, on medical matters formerly assumed to be an individual physician's prerogative. Who will be accepted as a client, and the protocols governing that person's care, are thus increasingly dictated by organisational rather than individual medical ethics.

The result is that civilian physicians and nurses are taught that the traditional Hippocratic values are at best a limited covenant increasingly interpreted as: ''do what you can within the boundaries set by corporate employers''. As one recent commentator put it: ''HMOs [health maintenance organisations] and insurance companies have put them [doctors] into a form of enslavement. They tell them how to practise; how long their patient should remain in the hospital; and what prescription drugs, medical tests, prevention measures, and treatments are allowed. Sadly, in many instances (practising medicine without a licence), they determine whether patients live or die''.[32] What Dr Tornberg did, in effect, was transpose to the military a more general diminution of professional medical responsibility already familiar to medical and nursing students, and young practitioners, in civilian life. Trained to accept the care parameters of a health maintenance organisation in Kansas City, why not accept the parameters dictated by military authority? In a war against ''evil'' in which a bounty had been posted—''dead or alive''—against opposition leaders, the likelihood of a challenge by young medical professionals in the military became as remote as the probability of a successful defence against orders issued by a chain of command stretching from the US president to Dr Tornberg.

CONCLUSION

At least since the battle of Solferino, medical professionals have served as a civilising bulwark against the savagery of war and its excesses. That tradition has been enshrined in a series of international agreements, covenants and treaties to which the US has been a signatory. Compliance with these agreements was declared as secondary to the dictates of military necessity in 2002. As a result, a strongly protective and proactive medical ethic enshrined was deemed inapplicable to care and treatment decisions by medical personnel serving in the US military.

While in theory all US military personnel have the right to refuse an illegal order a chain of memoranda and orders by the highest of US military and political officials redefined the parameters of legal treatment in a fashion that made it almost impossible for medical military personnel to successfully refuse superiors' orders as unlawful. I have argued that the acceptance of military directives violating medical ethics and international covenants was encouraged by the demonisation of the enemy by the US president and a more general dilution in civilian medicine of an ethic of physician responsibility for patient care. The result has been that, for the first time since the Nuremberg trials after the second world war, a major political power self consciously weaponised medicine as a tool for the progress of military goals while effectively removing the right of medical personnel to refuse participation in internationally proscribed actions on the basis of international treaties or professional ethics.

ACKNOWLEDGEMENT

This paper is based on a lecture presented on 10 February 2006 at the invitation of the University of Hawaii's Richardson School of Law. The author thanks members of that audience for their comments and suggestions as well as University of Hawaii Professor James Pietsch and University of Michigan professor Dr Howard Brody for their comments on an earlier draft of this article.

J Med Ethics 2006;**32**:249–252.
doi: 10.1136/jme.2006.016485

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Received 28 February 2006
Accepted for publication 2 March 2006

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Phase I oncology trials

Phase I oncology trials: why the therapeutic misconception will not go away

W Glannon

In many cases, the ''therapeutic misconception'' may be an unavoidable part of the imperfect process of recruitment and consent in medical research

Paul Appelbaum, Loren Roth, and Charles Lidz coined the term ''therapeutic misconception'' in 1982.[1] They described it as the misconception that participating in research is the same as receiving individualised treatment from a physician. It referred to the research subject's failure to appreciate that the aim of research is to obtain scientific knowledge, and that any benefit to the subject is a by-product of that knowledge. More recent studies by Appelbaum and Lidz have shown that this phenomenon is just as pervasive now as it was twenty four years ago.[2] The problem pertains not to any duty of care for researchers but to participants' unfounded belief in the therapeutic potential of research.[3] It is especially acute in phase I oncology trials, which aim to test the toxicity and highest tolerable dose of anticancer drugs.

To remedy this situation, many have argued that both clinicians and researchers need to do more in explaining to subjects the differences between experimental research and standard care. Clinicians and researchers recruiting potential subjects for research must present information about the expected risks and benefits of participation in research in a more realistic and straightforward way.[4] In one recent examination of consent forms for phase I oncology trials, Sam Horng *et al* found that, in the section on ''benefit'', only one of 272 forms stated that the subjects were expected to benefit. They also found that 11 consent forms (four per cent) stated clearly that subjects would not benefit, 25 forms (nine per cent) communicated uncertainty about benefit, and 5 forms (two per cent) said nothing about the chance of benefit. Interestingly, 139 forms (51 per cent) alluded to the possibility of benefit in a section other than the designated ''benefit'' section.[5] In the light of this, it is imperative that all phase I consent forms prominently state that the research is not expected to benefit the participant. More specifically, they should state that there is an overall complete response rate of 0.5 per cent and a partial response rate of 1.5 per cent (total response rate two per cent) in phase I oncology trials.

Nancy King has proposed that we distinguish three types of research benefit: direct benefit, collateral benefit, and aspirational benefit.[6] Direct benefit is defined as benefit that results from the subject receiving the intervention being studied, or its therapeutic physiological benefit. Collateral (or indirect) benefit results from being a subject in a trial, even if one does not receive the experimental intervention. Collateral benefit can be physiological or psychological and includes what is known as ''inclusion benefit'', the benefit gained from participation itself. Aspirational benefit is the benefit to society and

future patients, which follows from the results of the study. King points out that research subjects often confuse these different senses of ''benefit''.

In many cases, it is the desire or hope for direct benefit, a positive physiological response, which motivates people to participate in medical research. Even if clinicians and researchers carefully explained the differences between clinical care and research to patients, and even if consent forms prominently stated that subjects were not likely to benefit from participating in research, it would reduce the incidence of, but not eliminate, the therapeutic misconception. Indeed, it would be naïve to think that it could be prevented in every case. This misconception is one manifestation of a deep seated phenomenon of human psychology: the unique combination of emotion and reason in individual decision making.

How an investigator or clinician explains information about research must not be equated with how a subject processes and interprets that information. What the information means to the subject is not solely a function of how it is presented. In addition, it depends on beliefs and emotions such as fear and hope. These emotions can and often do influence how a subject interprets medical information, particularly with respect to the weighing of risks and benefits of participating in research, as well as what the subject expects from participating. Depending on how they present and explain this information, researchers can influence a potential subject's reasoning. They cannot, however, determine how the subject's emotions ultimately figure in the decision whether or not to participate in a clinical trial. There are both objective and subjective components to how one interprets medical research. The subjective component can play a significant role in a person's deliberation and decision about whether or not to enter a trial.

There is more to rationality and decision making about whether to take part in medical research than the presentation of information about the research. Reason and emotion are interdependent and mutually influencing mental capacities. Some of this influence occurs outside of our conscious awareness, and it is not only negative but can be positive as well. Positive emotions such as joy and negative emotions such as fear are essential to planning and choosing in accord with one's short and long term best interests. It is thus misleading to think that people make purely cognitive decisions about participation in medical research solely on the basis of the medical information presented to them by researchers.

Whether a decision to participate in research is rational and meaningful for the subject is not determined by the information alone, but also by her unique cognitive/emotional response to it. This response may be influenced by social or familial factors. For example, an individual without medical insurance in the United States may enter a clinical trial believing that it is the only way to receive medical care. Also, parents of a terminally ill child with advanced cancer may feel obligated to do everything medically possible for their son or daughter. This may involve entering their child in a phase I oncology trial. Generally, the decision of a competent adult with a disease to enter a clinical trial is rational and meaningful for her when she believes and hopes that participating is in her best interests. These include not only her best medical interests, but also her best interests regarding her life as a whole. Moreover, participating may be rational and meaningful for her because she believes and hopes that it will lead to a cure for people who will be afflicted with her disease in the future. The interaction of beliefs and emotions is part and parcel of rational processing and decision making. Thus the presence of emotion as such in decision making does not necessarily refract the information conveyed to the subject to the point of misconstruing what is presented.

Still, the information may be misconstrued if the emotions are excessive and not in line with reasons for or against acting on the information. This may occur if the subject's positive emotions make him overly optimistic about a cure, and especially if the negative emotion of fear makes him desperate for one. What exacerbates this problem in phase I trials is that they are offered to people when all other treatment options have been exhausted. Excessive positive or negative emotions can distort rational judgment. In examining the psychological factors behind this misconception, it is important not to confuse the qualitative benefit that a participant might derive from believing that he is contributing to science with the qualitative benefit derived from believing that participation in a phase I trial will lead to a cure. Any qualitative benefit based on hope or desperation may very well be illusory. These types of cognitive/emotional states are largely responsible for the misconception many participants have about these trials.

The results of one study of the perceptions of cancer patients in a phase I oncology trial conducted by Charles Daugherty and colleagues at the University of Chicago are a good example of the therapeutic misconception. Thirty patients were surveyed. Although 93 per cent said they understood the information given to them, only 33 per cent were able to state that the purpose of the trial was to determine toxicity, tolerability, or the safest dose of the drug that was administered. Less than one third of the participants said the research team discussed the option of no treatment but supportive care with them. Only a few participants said they were motivated by altruism. Eighty five per cent said they had decided to participate for the reason of possible therapeutic benefit.[7] This last fact by itself is not problematic. What *is* problematic is that there was no evidence that this majority of participants did any weighing of the potential benefits and risks of participating in the study. These results may be generalised to a larger number of research subjects in similar trials. They also underscore the obligation of researchers not to mislead subjects about potential benefits in these trials and instead to emphasise their non-therapeutic purpose. Oncologist Matthew Miller spells out what this obligation entails:

> We cannot continue to claim that, since the novel agents under investigation have never before been used in humans, any dose is potentially therapeutic. The opposite is true. Unless and until we know whether a given drug is effective, under what conditions, for which malignancies, and at what dose, these trials remain non-therapeutic and ought to be spoken of as such.[8]

A fair and accurate presentation of information about a phase I anticancer drug trial must include mention of any efficacy in animal models and in vitro studies. It must also include data on response rates to anticancer drugs in human subjects. An adult participant or parent of a child may seize upon the mention of ''efficacy'' or ''benefit'' in the investigator's explanation and in the consent form, paying little or no attention to the ''not likely'' that may precede or follow it. This may be due to people's tendency to confuse a phase I trial with phase II and III trials, where research and therapy may overlap to some extent.[9] Unlike early stage trials, subjects in more advanced trials may benefit from participating in them. What reinforces this confusion is the tendency among some subjects to perceive the researcher as a physician, as someone to whom they stand in a therapeutic relationship. They may

identify the researcher as someone from whom they will receive medical care.

The misconception about efficacy may also be a reflection of the subject's belief in and hope of receiving a benefit. From a neutral third party perspective, the possible benefit may be negligible. Yet for the subject it may be significant, and participation in a trial on this basis cannot be dismissed out of hand as uninformed or irrational. The subject may believe that, for *him* or *her*, the possible benefit of participating in the trial, however slight, outweighs the risks. These risks include not only physiological side effects of drug toxicity, but also the emotional side effects of the defeat of hope for one last chance of remission or cure. These risks may be rational to take when one is facing imminent death. However, a rational therapeutic optimism consisting in weighing low probable benefit against risk should be distinguished from an irrational therapeutic misconception. In the latter, there is no careful weighing of low probable benefit against risk, but a belief in a direct benefit without much, if any, consideration of risk.

To be sure, researchers and clinicians should do more to encourage informed decision making among research subjects. We must not encourage flawed decisions simply because we humans continue to make them. In particular, we should try to limit the influence of negative emotions such as fear or desperation in subjects' decision making as much as possible. We must not, however, be misled into thinking that more careful presentation of information about research will eliminate the tendency among subjects to conflate research and therapy. Informed consent is an imperfect process of communication between researchers and subjects involving more than a value neutral presentation and explanation of medical information. It also involves a value laden interpretation of that information by subjects in virtue of their cognitive/emotional state of mind, which can be and often is influenced by their unique personal situation.

Admittedly, if more potential subjects clearly distinguished between research and therapy and believed that the probable benefit from research was low or negligible, then this might adversely affect the motivation for participation in clinical trials. The consequence of this for phase I oncology trials could be significant, as there could be a reduction in the number of people entering these trials. This in turn could have a negative impact on the development of more effective and safer drugs and procedures, since the multistage process necessary to test the safety and efficacy of experimental treatments might be pre-empted from the start. Studies like the one conducted by Daugherty *et al* suggest that only a small percentage of research subjects are motivated by altruism to participate in phase I trials.[10] Many are motivated by emotions such as fear of dying and hope of a remission or cure. This phenomenon may allay concerns about ensuring adequate enrolment in clinical trials. But it clearly would not be the most desirable way of achieving this goal if the emotions involved in one's decision to participate in a trial were based largely on an illusory sense of benefit.

One promising strategy for improving participants' understanding of research is to have a study team member or a neutral educator spend more time explaining the design and purpose of the research with each potential participant.[11] This could include testing subjects' comprehension during the informed consent process. Yet even if researchers did more to discourage the therapeutic misconception, many subjects would continue to think of clinical trials as therapeutic and would continue to participate on this ground. The subjective and situational aspects underlying this thinking and the reasons for participation cannot be factored out of the decision making process. So the possibility of a substantial reduction in the number of people entering trials is not likely to be realised.

Alternatively, researchers could tolerate the therapeutic misconception for the pragmatic reason of ensuring adequate enrolment in clinical trials. This second option is more ethically objectionable than the first. By focusing only on the goal of adequate enrolment, researchers would be disingenuous in explaining the reasons for participating in the research and in trying to persuade potential subjects to participate. This pragmatic option would be ethically indefensible if it amounted to encouraging people to take risks of physiological and psychological harm when they have false beliefs about the effects of an experimental agent.

A third option would be to pay people to participate in clinical trials. This might send the message that they were participating in these trials for the sake of science and should be compensated for it, which would not occur if they were acting because they expected to benefit from it.[12] Some might question this remunerative option, arguing that it could result in payment being a coercive offer to a vulnerable patient population such as the poor or uninsured. It could be an incentive to take risks in exchange for money. This would not necessarily follow, though. As Christine Grady points out, an amount of money that is not excessive and is calculated on the basis of time and contribution would not constitute an undue inducement.[13] Instead, it would show respect for the contribution that subjects make to research and to the common good.[14] Nevertheless, this option at best would ameliorate but not resolve the problem of misperception about research.

In recruiting subjects for a phase I oncology clinical trial, researchers are obligated to explain the design and purpose of the trial to them as clearly and carefully as possible. This includes trying to dispel any perceived or apparent misconception people might have about the trial. Consent forms must also explicitly state the design and goals of the trial, as well as the potential benefits and risks. These forms should also include data on response rates and adverse events. Although the efforts of researchers may lower the incidence of the therapeutic misconception among research subjects, many subjects will continue to believe they can benefit from participating in clinical trials. Certain emotions and other psychological features of the thought processes of subjects will remain beyond the control of researchers, regardless of the steps they may take to try to dispel any misconception about research. So the problem will not likely be eliminated. In many cases, the therapeutic misconception may be an unavoidable part of the imperfect process of recruitment and consent in medical research.

ACKNOWLEDGEMENT

I am grateful to Dr Lainie Friedman Ross for helpful comments and suggestions on earlier drafts of this paper.

J Med Ethics 2006;**32**:252–255.
doi: 10.1136/jme.2005.015685

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Received 16 December 2005
In revised form 20 February 2006
Accepted for publication 23 February 2006

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ECHO

Doctors decide disclosure of sudden unexplained death

Please visit the *Journal of Medical Ethics* website [www.jmedethics.com] for a link to the full text of this article.

British neurologists are guided by their judgement, not published guidelines, in telling patients about sudden unexplained death in epilepsy (SUDEP), a survey discloses.

National Institute for Health and Clinical Excellence (NICE) guidelines advocate that patients and their families and carers should be given this information. In reality, practice among neurologists differs, with only 5% complying, most (61%) telling a few patients, a quarter telling most, and 8% telling none. Neurologists with an interest in epilepsy were more likely to comply, maybe because of familiarity with the guidelines. They were less likely to report a negative reaction, maybe being more at ease about the disclosure or their patients having come across the subject before. Years as a doctor or seniority did not affect the findings. About half the respondents discussed SUDEP in just one circumstance—when patients asked—otherwise it was when patients asked or if they had risk factors for SUDEP. Almost all thought that patients did not understand relative risks for SUDEP well; nearly half (47%) did not consider that knowing about SUDEP affected patients' quality of life; but a third thought that broaching the subject caused anxiety.

The response rate was 82% for consultant neurologists and about 19% for specialist registrars.

NICE guidelines do not advise how, when, and by whom information on SUDEP should be given. The prevailing view of medical leaders and patient groups is for as much as possible, covering every contingency, to be given up front, denying patients' right not to know.

▲ Morton B, *et al*. *Journal of Neurology, Neurosurgery, and Psychiatry* 2006;**77**:199–202.